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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/700,713	11/27/2000	Genichiro Soma	101149-00008	7273

6449 7590 07/28/2003

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EXAMINER

SHAHNAN SHAH, KHATOL S

ART UNIT	PAPER NUMBER
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1645

DATE MAILED: 07/28/2003

21

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application N

09/700,713

Applicant(s)

SOMA ET AL.

Examiner

Khatol S Shannan-Shah

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 05 May 2003.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1,2,4,6,9,10 and 15-17 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1,2,6,9,10 and 15-17 is/are rejected.
- 7) ☒ Claim(s) 4 and 17 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). _____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other:

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DETAILED ACTION

1. Applicants' amendment C, received May 05, 2003, paper #20 is acknowledged. Claims 3, 5 and 11-14 were canceled without prejudice. Claims 1, 2, 4, 6, 9, 10, 15 and 16 were amended. New claim 17 was added. Specification page 1 was amended.
2. Currently claims 1, 2, 4, 6, 9, 10 and 15-17 are pending and under consideration.

Prior Citations of Title 35 Sections

3. The text of those sections of Title 35 U.S. Code not included in this action can be found in a prior office action.

Prior Citations of References

4. The references cited or used as prior art in support of one or more rejections in the instant office action have been previously cited and made of record. No form PTO-892 or form PTO-1449 have been submitted with this office action.

Objections Withdrawn

5. Objection to priority status made in paragraph 6 of the office action mailed December 04, 2002 is withdrawn in view of applicants' amendment.

Rejections Moot

6. Rejection of claim 12 under 35 USC 112 second paragraph, made in paragraph 14 of the office action mailed December 04, 2002 is moot in view of applicants' cancellation of the claim.
7. Rejection of claims 5, 11- 12 under 35 USC 102, made in paragraph 15 of the office action mailed December 04, 2002 is moot in view of applicants' cancellation of the claims.

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8. Rejection of claims 5, 11- 12 under 35 USC 102, made in paragraph 16 of the office action mailed December 04, 2002 is moot in view of applicants' cancellation of the claims.

9. Rejection of claims 5, 11- 12 under 35 USC 102, made in paragraph 17 of the office action mailed December 04, 2002 is moot in view of applicants' cancellation of the claims.

10. Rejection of claims 3, 5, 11- 12 under 35 USC 103, made in paragraph 18 of the office action mailed December 04, 2002 is moot in view of applicants' cancellation of the claims.

Rejections Withdrawn

11. Rejection of claims 6 and 15 under 35 USC 112 second paragraph, made in paragraph 14 of the office action mailed December 04, 2002 is withdrawn in view of applicants' amendments.

12. Rejection of claim 4 under 35 USC 102, made in paragraph 15 of the office action mailed December 04, 2002 is withdrawn in view of applicants' amendments.

13. Rejection of claims 1, 2, 6, 9-12 and 15-16 under 35 USC 103, made in paragraph 18 of the office action mailed December 04, 2002 is withdrawn in view of applicants' amendments.

14. Rejection of claim 4 under 35 USC 103, made in paragraph 19 of the office action mailed December 04, 2002 is withdrawn in view of applicants' amendments.

Rejections Maintained

15. Rejection of claims 1, 2, 6, 9, and 10 under U.S.C. 102(b) as being anticipated by Soma et al. (US Patent No. 5,346,891) is maintained.

Claims are drawn to a product prepared from gram negative bacteria, that has a molecular weight of 5000 ± 2000 as measured by SDS-PAGE method. The product is a low molecular weight lipopolysacchride and capable of activating immunity or prevent infection.

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Applicants' arguments filed 5/5/2003 have been fully considered but they are not persuasive.

Applicants argue, "The relevant claims have been amended and now recite "a feed" for fish or crustaceans which comprises a feedstuff additive, the feedstuff additive characterized in that it is prepared from gram negative bacteria. The cited references do not recite a feed and thus can not anticipate the claims as amended".

It is the examiner's position that the rejected claims are drawn to a product and the same product is taught by Soma et al. However, intended use does not impart any critical impact or weight on the physical preparation and the patentability of the product.

Soma et al. disclose a product prepared from gram negative bacteria, that has a molecular weight of 5000 ± 1000 as measured by SDS-PAGE method. The product is a low molecular weight lipopolysacchride and capable of activating immunity (see abstract).

Soma et al. disclose three products (novel lipopolysaccharides) from gram negative bacteria that have molecular weights of $5,000 \pm 1000$ and $6,500 \pm 2,500$ as measured by SDS-PAGE method. (see abstract and claims). The products has been used as immunity stimulators via oral administration for different animals. (see column 18 lines, 25-60 and claims 4-6). Soma et al. teach a 96% pure LPS with the dominant molecular weight of 5000 ± 1000 as measured by SDS-PAGE (see columns 3-4). One of the lipopolysaccharide is produced by a strain of the species *Pantoea agglomerans* (see column 8 line 65 and claim 3). Soma et al. teach an agent for activating immunity comprising the lipopolysaccharide and pharmaceutically or veterinary acceptable carrier (see claims 4-6). Soma et al. teach, "The present invention is intended to provide novel veterinary immunity-

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stimulating agents (column 2, lines 54-60) and the invention may be used separately or in admixture in food, drinks and feed (column 5, lines 40-50). Thus the prior art anticipates the claimed invention and its limitations.

Since the office does not have the facilities for examining and comparing applicants' product with the product of the prior art, the burden is on the applicant to show a novel or unobvious difference between the claimed product and the product of the prior art (i. e., that the product of prior art does not possess the same material structure and functional characteristics of the claimed product). See In re Best, 562 F.2 d 1252, 195 USPQ 430 (CCPA 1977) and In re Fitzgerald et al., 205 USPQ 594.

16. Rejection of claims 1, 2, 6, 9, and 10 under U.S.C. 102(b) as being anticipated by Mizuno et al. (WO96/23002) is maintained.

Claims are drawn to a product prepared from gram negative bacteria, that has a molecular weight of 5000 ± 2000 as measured by SDS-PAGE method. The product is a low molecular weight lipopolysacchride and capable of activating immunity or prevent infection.

Applicant's arguments filed 5/5/2003 have been fully considered but they are not persuasive.

Applicants argue, "The relevant claims have been amended and now recite "a feed" for fish or crustaceans which comprises a feedstuff additive, the feedstuff additive characterized in that it is prepared from gram negative bacteria. The cited references do not recite a feed and thus can not anticipate the claims as amended".

It is the examiner's position that the rejected claims are drawn to a product and the same product is taught by Mizuno et al. However, intended use does not impart any critical impact or

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weight on the physical preparation and the patentability of the product.

Mizuno et al. teach a product prepared from gram negative bacteria, that has a molecular weight of 5000 ± 1000 as measured by SDS-PAGE method. The product is a low molecular weight lipopolysaccharide being substantially free from other molecular weights and capable of activating immunity and preventing infection (see abstract). Mizuno et al. teach low molecular weight lipopolysaccharide from *Pantoea* species.

Since the office does not have the facilities for examining and comparing applicants' product with the product of the prior art, the burden is on the applicant to show a novel or unobvious difference between the claimed product and the product of the prior art (i. e., that the product of prior art does not possess the same material structure and functional characteristics of the claimed product). See In re Best, 562 F.2 d 1252, 195 USPQ 430 (CCPA 1977) and In re Fitzgerald et al., 205 USPQ 594.

17. Rejection of claims 1, 2, 6, 9, and 10 under U.S.C. 102(b) as being anticipated by Soma et al. (US Patent No. 5,494,819) is maintained.

Applicants' arguments filed 5/5/2003 have been fully considered but they are not persuasive.

Applicants argue, "The relevant claims have been amended and now recite "a feed" for fish or crustaceans which comprises a feedstuff additive, the feedstuff additive characterized in that it is prepared from gram negative bacteria. The cited references do not recite a feed and thus can not anticipate the claims as amended".

It is the examiner's position that the rejected claims are drawn to a product and the same product is taught by Soma et al. However, intended use does not impart any critical impact or

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weight on the physical preparation and the patentability of the product.

Claims are drawn to a product prepared from gram negative bacteria, that has a molecular weight of 5000 ± 2000 as measured by SDS-PAGE method. The product is a low molecular weight lipopolysaccharide and capable of activating immunity or prevent infection. The product is intended to be used as a feedstuff additive for crustaceans and fish.

However, intended use does not impart any critical impact or weight on the physical preparation and the patentability of the product.

Soma et al. (US Patent No. 5,494,819) teach a product prepared from gram negative bacteria, that has a molecular weight of 5000 ± 1000 as measured by SDS-PAGE method (see column 3). The product is a low molecular weight lipopolysaccharide and capable of activating immunity (see column 5). The product can be used as feed or feed additives for veterinary use. (see column 5).

Soma et al. disclose three products (novel lipopolysaccharides) from gram negative bacteria that have molecular weights of $5,000 \pm 1000$ and $6,500 \pm 2,500$ as measured by SDS-PAGE method. (see columns 3, 10, abstract and claim 1). The products can be used as immunity stimulators with acceptable carriers (see column 5 and column 17). Soma et al. teach a 96% pure LPS with the dominant molecular weight of 5000 ± 1000 as measured by SDS-PAGE (see columns 3). One of the lipopolysaccharide is produced by a strain of the species *Pantoea agglomerans* (see abstract and claim 1).

Soma et al. teach, "The LPSs according to the present invention may be used separately or in admixture with each other or together with any other substance (column 5, lines 5-8), for veterinary use, the agent may be prepared in the form of feed additives (column 5, lines 21-23), if

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desired these preparations may contain excipients (i.e. carriers) (column 5, lines 21-23)".

Thus the prior art anticipates the claimed invention and its limitations.

Since the office does not have the facilities for examining and comparing applicants' product with the product of the prior art, the burden is on the applicant to show a novel or unobvious difference between the claimed product and the product of the prior art (i. e., that the product of prior art does not possess the same material structure and functional characteristics of the claimed product). See In re Best, 562 F.2 d 1252, 195 USPQ 430 (CCPA 1977) and In re Fitzgerald et al., 205 USPQ 594.

New Grounds for Rejection

Claim Objections

18. Claim 17 is objected to because of the following informalities: SDS-PAGE is misspelled. Appropriate correction is required.

Claim Rejections - 35 USC § 112

19. Claim 6 is rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for certain doses of the claimed agent for activating immunity or preventing infection of crustaceans and fish and does not reasonably provide enablement for any amount encompassed by the claim. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to identify or make the invention commensurate in scope with the claim.

Claim 6 broadly, recites the phrase " an admixture of an immunity-activating or infection-preventing amount". It is not clear what applicants intend in recitation of said phrase. It is not clear from the specification how this amount is determined. The specification page 10

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recites that the LPS is administered at a daily dose of 1 to 100 μ g, preferably 10 to 20 μ g, per kilogram of the body weight of crustaceans or fishes. On page 14, table 1 the dosages are recited as 50 mg/kg or 100 mg/kg. It is not clear what are the lower and upper limits of the amount. Is any amount above 100 mg/kg is considered therapeutic or toxic? The range of doses from 1 μ g to 100 mg is very broad and wide. The specification is not clear in regard to immunity-activating or infection-preventing amount as recited in claim 6 and the instant specification invites the skilled artisan to experiment.

20. Claims 15-17 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Amended claim 15 recites, "wherein the infection is caused by disease". This is not clear. Infection is a disease.

The term "substantially" in claim 17 is a relative term, which renders the claim indefinite. The term "substantially" is not defined by the claim, the specification does not provide a standard for ascertaining the requisite degree, and one of ordinary skill in the art would not be reasonably apprised of the scope of the invention.

The term "capable" in claim 17 is a relative term, which renders the claim indefinite. The term "capable" is not defined by the claim, the specification does not provide a standard for ascertaining the requisite degree, and one of ordinary skill in the art would not be reasonably apprised of the scope of the invention.

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It is not clear what applicants intend in recitation of the phrase "characterized in that" in claim 17.

Claim Rejections - 35 USC § 102

21. Newly added claim 17 is rejected under U.S.C. 102(b) as being anticipated by Soma et al. (US Patent No. 5,494,819).

Claim 17 is drawn to a product, a feed comprising a feed additive prepared from gram negative bacteria, that has a molecular weight of 5000 ± 2000 as measured by SDS-PAGE method, that is a low molecular weight lipopolysaccharide and capable of activating immunity or prevent infection and a carrier. The product is intended to be used as a feedstuff additive for crustaceans and fish.

Soma et al. (US Patent No. 5,494,819) teach a product prepared from gram negative bacteria, that has a molecular weight of 5000 ± 1000 as measured by SDS-PAGE method (see column 3). The product is a low molecular weight lipopolysaccharide and capable of activating immunity (see column 5). The product can be used as feed or feed additives for veterinary use. (see column 5).

Soma et al. disclose three products (novel lipopolysaccharides) from gram negative bacteria that have molecular weights of $5,000 \pm 1000$ and $6,500 \pm 2,500$ as measured by SDS-PAGE method. (see columns 3, 10, abstract and claim 1). The products can be used as immunity stimulators with acceptable carriers (see column 5 and column 17). Soma et al. teach a 96% pure LPS with the dominant molecular weight of 5000 ± 1000 as measured by SDS-PAGE (see columns 3). One of the lipopolysaccharide is produced by a strain of the species *Pantoea agglomerans* (see abstract and claim 1).

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Soma et al. teach, "The LPSs according to the present invention may be used separately or in admixture with each other or together with any other substance (column 5, lines 5-8), for veterinary use, the agent may be prepared in the form of feed additives (column 5, lines 21-23), if desired these preparations may contain excipients (i.e. carriers) (column 5, lines 21-23)".

Thus the prior art anticipates the claimed invention and its limitations.

Since the office does not have the facilities for examining and comparing applicants' product with the product of the prior art, the burden is on the applicant to show a novel or unobvious difference between the claimed product and the product of the prior art (i. e., that the product of prior art does not possess the same material structure and functional characteristics of the claimed product). See In re Best, 562 F.2 d 1252, 195 USPQ 430 (CCPA 1977) and In re Fitzgerald et al., 205 USPQ 594.

Conclusion

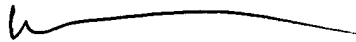
22. Claims 1, 2, 6, 9, 10 and 15-17 stand rejected.

Claim 4 is objected to as being dependent from rejected base claim 1.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Khatol Shahnan-Shah whose telephone number is (703) 308-8896. The examiner can normally be reached from 7: 30 AM - 4 PM on Monday through Friday. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Lynette F Smith, can be reached on (703) 308-3909. The fax phone number for the organization where this application or proceeding is assigned to is (703) 305-3014.

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Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

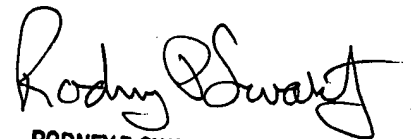


Khatol Shahnan-Shah, BS, Pharm, MS

Biotechnology Patent Examiner

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RODNEY P SWARTZ, PH.D
PRIMARY EXAMINER